DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Original M31/100 W
Signed
HFE-35

One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.279.1675
Fax 781.279.1742

November 12, 1999

WARNING LETTER

NWE-06-00W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John T. Sullivan, President
Pier 7, Inc.
23 Foodmart Road
Boston, MA 02119

Dear Mr. Sullivan:

On October 20, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 23 Foodmart Road in Boston, MA. The inspection revealed that the fresh tuna being processed by your firm is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The adulteration is due to deviations from the regulation governing procedures for the safe and sanitary processing and importing of fish and fishery products (seafood HACCP[1]), Title 21 Code of Federal Regulations, Part 123 (21 CFR § 123).

The following deviations from the HACCP regulation were noted:

- Monitoring record data are missing for the receiving step, a Critical Control Point (CCP), in your firm's HACCP plan for fresh tuna. This is a requirement under 21 CFR § 123.6(c)(7). No records were available for whole tuna received on or about October 19, 1999 from [redacted] in [redacted] MA, or for fresh tuna imported from Venezuela on or about October 13, 1999.

[1] Hazard Analysis Critical Control Point. HACCP entails (1) identifying food safety hazards that, in the absence of appropriate controls, are reasonably likely to occur in your products and (2) having these controls at "critical control points" during processing to eliminate or minimize the likelihood that the identified hazards will occur.

- You have not developed a HACCP plan for the storage of vacuum packed salmon. Storage is considered processing under the 21 CFR Part 123. A written HACCP plan is a requirement under 21 CFR § 123.6(b).

The deviations identified above are not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure that your firm and its products are in compliance with applicable regulations and laws enforced by FDA. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by FDA without further notice. These actions may include seizure or injunction under the FD&C Act.

This inspection also revealed that your firm has no product specifications or other written verification measures for vacuum packed smoked salmon imported from Norway. These are requirements under 21 CFR § 123.12(a)(2).

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed with 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Mark Lookabaugh, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, MA 02180. If you have any questions concerning this notice, please contact Mr. Lookabaugh at ***781.279.1675 x118.***

Sincerely,

John R. Marzilli
Director
New England District